PITT STREET RESEARCH

TruScreen Group Ltd

Share Price: NZ$0.033

Detecting cervical cancer

TruScreen Group Ltd (NZX/ASX: TRU) is a medtech company that is commercialising the TRU system. TRU is a device that can detect cancer or pre-cancerous changes in cervical tissues. It provides an non-invasive, more objective and faster method compared to the conventional Pap smear test that requires collection of tissue samples from the cervix.

A non-conventional commercialisation approach

Unlike many other ASX medtechs, which are seeking to commercialise their devices in developed countries, TruScreen is focused on developing countries such as China, Mexico, Vietnam and Zimbabwe. The advantage is that there is no large-scale cervical cancer screening programs and infrastructure. This enables quicker market penetration given a lack of existing competition and because TRU is more 'capital light', not requiring lab infrastructure. Over the last few years, it has demonstrated fast uptake and market penetration given limited existing competition.

Progress has been made since 2020

Since we last covered TruScreen in late 2020, TRU has made significant progress in spite of the difficulty that the pandemic presented. The device has received further clinical validation and the company has expanded its footprint in existing and emerging markets. During FY22, over 170k TRU examinations were performed across the world. By next month, the company aspires to have 265 devices installed globally, up 70% in 2 years. We are optimistic about the company's prospects in the years ahead.

Valuation range of NZ$0.065 – NZ$0.133 per share

We value TRU at NZ$0.065 per share base case and NZ$0.133 in an optimistic case using a DCF methodology, based on the assumptions of market share growth in its existing and potential geographies. Key risks, as outlined on page 17, include funding risks, regulatory risks, execution risks and technology risks.

NZX: TRU

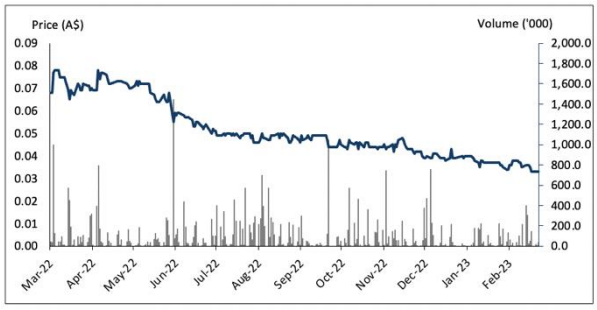
Sector: Healthcare Equipment & Services

7 March 2023

Market Cap. (NZ$ m)	15.2
# shares outstanding (m)	459.4
# shares fully diluted (m)	464.4
Market Cap Ful. Dil. (NZ$ m)	15.3
Free Float	88.3%
52-week high/low (NZ$)	0.078 / 0.028
Avg. 12M daily volume ('1000)	130.9
Website	www.truscreen.com

Source: Company, Pitt Street Research

Share price (NZ$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (NZ$)	0.065 – 0.133
WACC	15.8%
Assumed terminal growth rate	2.0%

Source: Pitt Street Research

Analysts: Stuart Roberts, Nicholas Sundich

Tel: +61 (0)447 247 909

stuart.roberts@pittstreetresearch.com

nick.sundich@pittstreetresearch.com

Table of Contents

Introducing TruScreen, ASX: TRU

The TRU device is an opto-electrical, real-time and single-use cervical cancer screening system

TruScreen Group Ltd (NZX: TRU) is is a New Zealand-based, ASX/NZX listed medtech company that has a real-time portable cervical cancer screening system, named after the company. The TRU system is based on an opto-electrical technology, and comprises a unique medical device, artificial intelligence algorithm technology and processes designed to detect the presence of pre-cancerous and cancerous tissues in the cervix.

What is the TRU System and how does it work? The TRU system consists of a handheld device (HHD), intelligent cradle and a single-use-sensor (SUS) (Figure 1 and 2). TruScreen device uses low level electrical and optical signals to detect cancerous and pre-cancerous tissues. The HHD collects and analyses the data and provides instant results, enabling clinicians/physicians to immediately plan appropriate patient care. The device has an expected life of 5–7 years, while the SUS is used once per test per patient. Having the sensor as a single-use product ensures there is no chance of cross-infection between patients or a build-up of protein or mucus on the sensor to be used that would affect results. The whole data collection and analysis is self-checked and controlled. No tissue sample is needed to be taken. These ensure that the result is reliable, consistent, and examination is painless and safe.

Figure 1 : TRU system – charging station, console and single use sensor

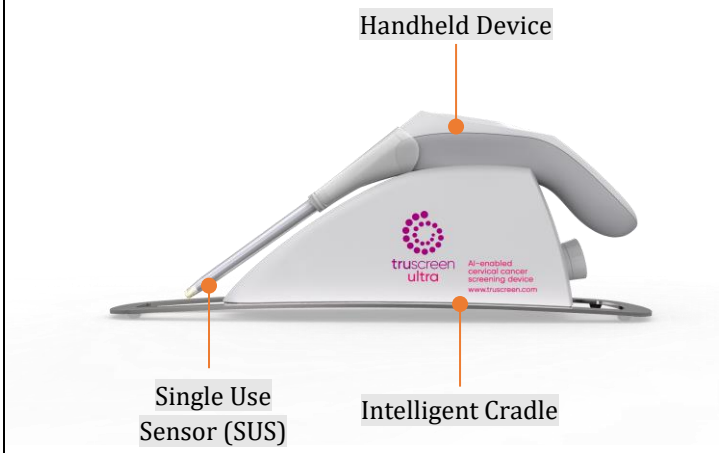


Figure 2: In-box TRU device

Source: Company

TRU has wide applications in Low and Middle-Income Countries (LMICs) where women lack access to low-cost cervical cancer screening

How is the TRU system superior to alternative screening methods? TRU represents a superior alternative to the conventional tests, such as Pap smears or liquid based cytology (LBC), which require tissue samples from the cervix, follow-up and high quality laboratory infrastructure to process and analyse the tissue samples, and achieve high accuracy.

As a result, TRU has wide application in Low and Middle-Income Countries (LMICs) where women typically lack access to cervical cancer screening. This real-time, single-visit and mobile screening technology does not require any high-cost lab infrastructure and can be conducted by a nurse or trained person based on local healthcare rules. TRU system is presently certified for use throughout Europe and has approval for sale in China, Vietnam, Mexico, Russia, Saudi Arabia and Zimbabwe, with China being the company's largest market.

What progress has been made since late 2020? TruScreen has three major achievements. Firstly, the company has grown both its revenues, the devices installed and consequently, the SUS sales. Secondly, the TRU device has gained further validation in the publication of five clinical papers and the passage of a major clinical trial in China, run by the Chinese Obstetricians and Gynaecologists Association (COGA). Thirdly, the company has increased the potential distribution pipeline, in existing and new markets.

Ten key reasons to look at TRU

1. **TRU technology, represents a better alternative to conventional a Pap test.** This is because TRU is non-invasive (no tissue collected), more objective (Artificial Intelligence, AI, driven algorithm) and delivers results faster (immediately after examination).
2. **The TRU system is more effective than its peers.** TRU relies on opto-electrical technology for the detection of cancerous cells as well as an AI algorithm. It detects abnormal tissue measurement results in real time.
3. **The system has been extensively tested,** and results of clinical trials with over 40000 women participating to date, reiterate that the system is comparable to hospital-based LBC. Most importantly, it has received CE Mark approval enabling the sale of the device in the European Union and proving the efficacy of the device. Recent, major clinical trial in China, run independently by the Chinese Obstetricians and Gynaecologists Association (COGA) on 15000 women have again confirmed the performance of the system. In financial year 2022, over 170,000 examinations have been performed, based on SUS sales. To date, over 260 devices have been installed and used globally.
4. TRU has a **focus on developing countries** which means it is likely to gain traction faster rather than in existing, more developed markets. The TRU system does not require any high-cost lab infrastructure or substantial operator training, thereby making it ideal for developing markets, particularly TRU's markets.
5. TRU **is likely to benefit from increased efforts to fight cervical cancer globally.** The World Health Organisation has set a target to eliminate cervical cancer by the end of the century. To help achieve this, it is targeting 70% world-wide coverage of screening and 90% treatment of precancerous lesions. TRU already plays a significant part in these endeavours, for example, in Zimbabwe.
6. **TRU's has a solid revenue model** that enables upfront revenue (from the device sale) and ongoing revenues (through single-use sensors). The SUS sales are likely to become a most important source of revenue as the clinical adoption of technology become widespread.
7. **TRU pursues a co-investment model with local distributors.** It outsources its in-country sales and marketing activities to its distributors. Additionally, its distributors invest heavily – along with the company – in clinical trials in numerous countries. Thus, a low-risk and highly scalable growth strategy is deployed by the company in its quest to grow in LMICs.
8. **We believe that the diverse and substantial experience of the current management and board members** will aid the company significantly in its commercialisation journey across multiple countries.
9. **Significant commercial progress has been made in the last couple of years.** Since our last report on TRU, the company has grown both its revenues and devices installed. Additionally, the TRU device has gained further validation in the publication of five clinical papers.

10. **We believe TRU is undervalued.** Our intrinsic value for TRU comes out to be NZ$0.065 in our base case and NZ$0.133 in our optimistic case. We believe re-rating will be driven by further commercialisation in key target markets.

The TRU technology

TRU was first conceived in 1986 but it took over 2 decades to bring the idea into reality. It consists of three components: the testing hand held device (that has a pen-like wand) and charging cradle/console unit and the consumable SUS. The system utilises proprietory technology to detect pre-cancerous change, or cervical intraepithelial neoplasia (CIN), by optical and electrical measurements of cervical tissue (Figures 3 and 4 on page 6).

TRU's development

It was initially developed at Sydney University, but the concept (first known as Polar Probe, and later TruScreen) was acquired by Polartechnics (PLT). Although PLT made significant progress, it went into liquidation in 2010 as funding dried up during the aftermath of the Global Financial Crisis. After PLT went bust, its assets (including all the intellectual property, inventory and commercial assets) were bought and eventually found their way into the company that owns it today.

The first generation of the TruScreen device was commercialised and launched to the market in 2003, after receiving CE Mark certification in 2002. A second generation, TruScreen Ultra ® was launched later with several improvements including significantly increased processing capacity, improved performance, wi-fi connectivity and an LCD touchscreen.

How TRU works

The testing hand-held device touches various spots on the cervix to send and receive low-level electrical and optical signals from the cervical tissue.

The testing handheld device touches various spots on the cervix to send and receive low level electrical and optical signals to and from the cervical tissue. A disposable SUS with precision lens and electrodes is used to interface with the cervix and protect against cross-infection.

TRU provides a binary classification result, classifying the cervical tissue collected as either Normal or Abnormal compared to a proprietary database of over 2,000 patients drawn from a wide range of geographic and ethnic backgrounds and it does so on the spot. Timely screening allows pre-cancerous lesions to be identified at nascent stages and early treatment is likely to prevent up to 80% of the cervical cancer cases in LMICs.

Unlike conventional cytology tests, the TRU device does not examine only surface epithelial cells – light at specific frequencies is transmitted through cervical tissue for identifying changes in the basal and stromal layers (Figure 3 and 4 on page 8).

The system also assesses the electrical properties and response of the tissue. The electrical measurements are stimulated by the delivery of a very small impulse (about one volt) in millisecond pulse sequences that repeat 14 times per second. The decay response curve (Figure 4 on page 6) will vary according to the capacitance of the tissue – a measurement of the ability of the tissue to either hold or dissipate a charge. Decay curves are then compared to distinguish between normal or abnormal tissues.

Figure 3: TRU consoles emits optical frequencies that refracts through cervical layers and relays back tissue decay readings

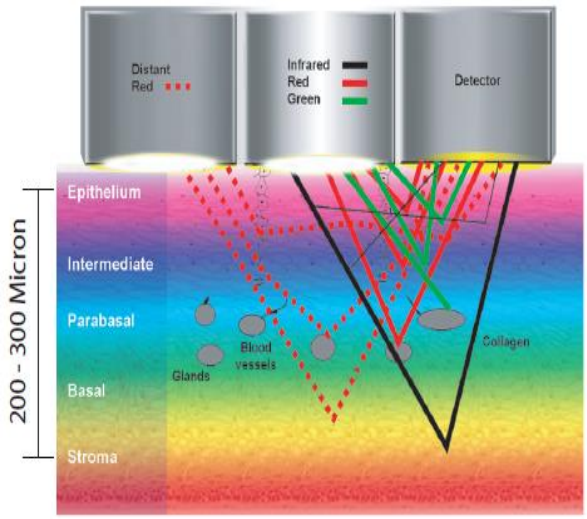
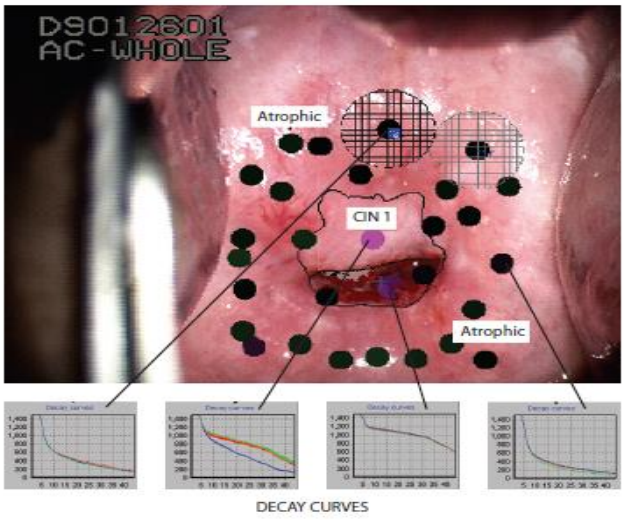


Figure 4: TRU HHD emits electrical signals frequencies. Electrical decay curves and tissue capacitance



Source: Company

TRU's validation

TRU has received extensive validation. In particular, it has received CE-Mark certification meaning it meets EU safety, health and environmental protection standards required for sale and use throughout Europe. It is also registered for use with the Australia's Therapeutic Goods Administration (TGA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA), New Zealand's Medsafe and Web Assisted Notification of Devices (WAND), Mexico's Federal Commission for Protection Against Health Risks, China's National Medical Products Administration (NMPA). It has Ministry of Health approval for use in Vietnam, Zimbabwe, Israel, Ukraine and the Philippines among others.

TRU has also received independent clinical validation on over 40000 women to date. Recently, the Chinese Obstetricians and Gynaecologists Association (COGA) run independently a major clinical trial in China, between September 2018 and July 2021. The trial, which screened 15,611 women across 64 hospitals in 9 provinces over 3 years, found that TRU's specificity surpassed Liquid Based Cytology (LBC) and high risk human papilloma virus PCR test (hrHPV). The study reported that for the detection of cervical carcinoma with grading CIN2+, TRU's sensitivity was higher than that of LBC, 87.5% vs 66.5% and specificity was higher than that of LBC and hrHPV testing, 88.4% vs 86.3% and 78.3%.

COGA specifically noted at the release of the results of the trial (at an April 2022 American Society of Colposcopy and Cervical Pathology Annual Congress, the major world conferenece in the field) that TRU is appropriate as a primary screening tool in regions with high morbidity and mortality to cervical cancer. This was because TRU minimises the need for training and facilities and offers a real-time result. Cytology- based tests, on the other hand, cannot be effective in mass population screening due to resource restrictions, such as costly infrastructure, training requirements for personel, loss of follow up and delays in receiving results.

Cervical cancer

Cervical cancer is the fourth most common cancer in women worldwide.

Cervical cancer is the growth of abnormal cells in the lining of the cervix. It is the fourth most common cancer in women worldwide - over 600,000 women are diagnosed with cervical cancer annually and the disease claims over 300,000 lives[1].

Cervical cancer is a particular problem in LMICs as over 90% of cervical cancer cases are detected there. Furthermore, it is the most diagnosed cancer in 23 countries and the leading cause of cancer death in 36 countries. World Health Organisation data also depicts a significant growth in both cases and deaths – 5.5% and 9.9% respectively between 2018 and 2020. The pandemic has exacerbated the problem given the lack of healthcare capacity to conduct asymptomatic cervical cancer screening. It has been estimated that there were 49% fewer high-grade cytological abnormalities diagnosed each month between March and December 2020 compared to pre-pandemic levels[2].

TRU can help with the WHO's goal to eliminate cervical cancer

In October 2019, the WHO set the goal to eliminate cervical cancer by the end of this century[3]. To achieve this goal, the WHO proposed that 70% of women between 35 and 45 years of age in all WHO member countries be screened with a high-precision test by 2030.

Countries will need to adopt innovative and optimal service delivery models, particularly in LMICs where cervical cancer incidence and mortality rates are higher because screening programs, infrastructure and resources are lacking.

Current cervical cancer screening methods

Cervical cancer can be treated and cured if detected early. But current screening methods have several shortcomings including invasiveness and cost.

Cervical cancer can be treated and cured if detected early through screening programs that look beyond mere physical symptoms. However, the later it is detected, the more difficult it is to fend off. Furthermore, current screening methods have several shortcomings including invasiveness and cost.

There are four primary cervical cancer screening methods.

A **Pap Test**, also known as a Pap Smear, is a conventional cytology method of screening that looks for cell changes in the cervix. It involves a doctor scraping a sample of cells from a patient's cervix. The sample is then sent to a laboratory to be tested for the presence of abnormal cells. This test is used quite commonly in LMICs.

When Pap Tests were invented in the 1920's, they were a significant breakthrough in women's health and have long been considered the golden standard in cervical screening.

Liquid Based Cytology (LBC) is a newer variation of the conventional Pap test. The cervical cells collected at the point of screening are suspended in liquid. This liquid sample is then sent to a laboratory where it is flited to remove unnecessary material and examined under a microscope. LBC is the test of choice in many advanced countries, including Australia

HPV DNA Testing is a more modern screening method. Unlike the Pap and LBC, HPV DNA testing tests for probability of cervical changes and not for cervical tissue abnormalities. HPV DNA test for the infection of high-risk HPV

[1] WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240030824

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9031697/

[3]World Health Organisation, Draft: Global Strategy Towards The Elimination Of Cervical Cancer As Public Health Problem, World Health Organisation, viewed 15 October 2019, https://truscreen.com/world-health-organisation-sets-global-agenda-to-eliminate-cervical-cancer/

strains. Due to the known relationship between persistent infection with high-risk (oncogenic) types of HPV (human papillomavirus) and the development of cervical cancer, testing for the presence of these HPVs can identify women at an increased risk of developing cervical cancer, however, it tells the woman nothing about the tissue changes on her cervix.

In HPV DNA testing, sample cells are examined in a laboratory for the genetic material of specific high-risk oncogenic HPV strains. If evidence of HPV is identified, HPV genotyping will be performed to determine the specific strain causing the infection. Although HPV DNA testing has started to dominate modern screening guidelines in high income countries, it is a quite expensive process that will not be affordable for population-based screening in many LMICs. It will increase populations of women identified as hrHPV positive who will also need further screening for cervical tissue changes evolve to advanced cervical cancer.

A **Visual Inspection** is commonly used in remote or low-resource settings, especially visual inspections with acetic acid (VIA) or visual inspection with acetic acid and camera (VIAC). A VIA begins with the cervix being swapped with a solution of dilute acetic acid (kitchen vinegar). The solution interacts with the cells on the surface of the cervix, this reaction is then visually inspected by the examiner. In VIACs, once the visual inspection is complete a camera with a special lens is used to photograph the cervix to help identify the presence of abnormal cells. VIA and VIAC are relatively inexpensive methods and provide immediate results. However, they are relatively non-specific and have low sensitivity. Over decades, the countries using VIA and VIAC have not observed decreased morbidity or mortality from the cervical cancer. VIA and VIACs are extremely reliant on the adequate training of the clinician performing the exam.

TRU's advantages over conventional cervical cancer screening methods

TRU has multiple benefits over the conventional Pap smear test.

TRU, with a unique position in the cervical screening space, has multiple benefits over the conventional Pap smear test. The closest competing technologies are cytology-based tests, i.e., conventional Pap smear and liquid-based cytology. In contrast to these methods, we see several advantages (Figure 5).

Figure 5: TruScreen's advantages

Feature	Benefit	Clinical Advantage
Real-time results	Immediate feedback to patient and operator	Patient can be treated if necessary at time of visit.Patient not lost to follow-up with delayed reporting
Objective result	Accurate result every time	Reproducible, consistent results to confirm accuracy
No lab facility needed	Greater access to women in remote communities. Easy to use	No qualified cytologists needed. Suitable for remote areas and developing countries. Cost savings in resources / overheads
High sensitivity	Assured level of performance. High standard of cervical screening	Improved ability to detect disease and save lives. Economic savings to global healthcare systems
Automated device and error-checking during examination	Consistent and accurate results	No chance of an unsatisfactory result
Tissue samples NOT collected	No pain or discomfort to the patient	Patient more likely to return for repeat screen

Source: World Health Organisation, Pitt Street Research, Company

Three are particularly noteworthy. First, that it provides real-time results. Second, it is non-invasive and painless. And third, the procedure need only be done once. For clinicians and healtcare providers, there are several benefits including that TRU's cost-effectiveness, the simplicity of training required prior to use and that TRU provides objective results without the woman needing to attend a second visit. Most importantly, TRU's overall sensitivity has been shown in several clinical trials to be equivalent or better to that of a Pap smear test. These advantages place TRU in good stead considering its commercialisation strategy.

TRU's opportunity

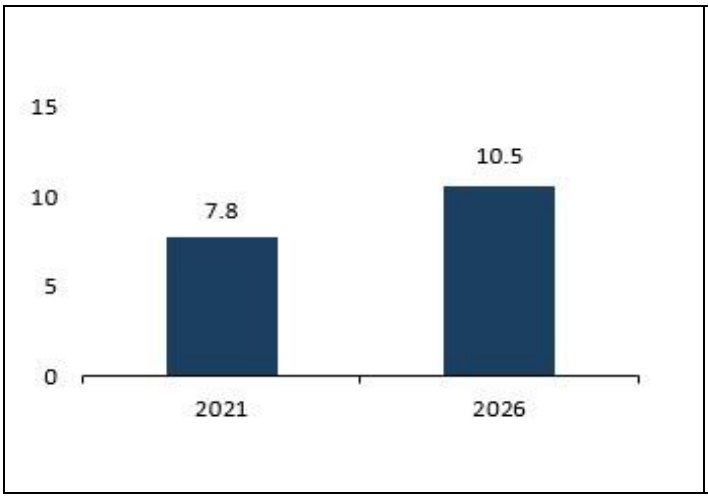
TRU has a significant market opportunity behind it. In this chapter, we quantify the opportunity and outline TRU's commercialisation strategy.

A significant untapped market exists

The global cervical cancer diagnostics market is expected to post a 6.2% CAGR to reach US$10.5bn by 2026.

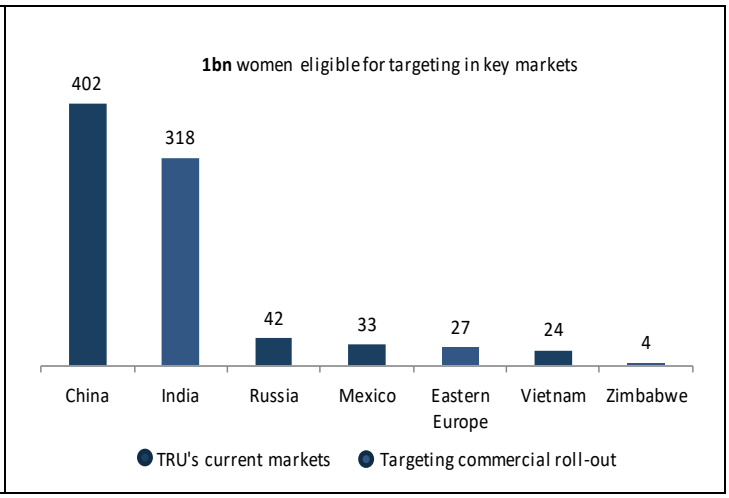
In February 2023, market intelligence firm ReportLinker valued the global cervical cancer diagnostics market (Figure 6) at ~US$7.9bn in 2021. It is expected to post a 6.2% CAGR to reach ~US$10.5bn by 2026. As we observed in the previous section, over 600,000 women are diagnosed with cervical cancer annually and the disease claims over 300,000 lives[4]. Over 90% of new cases and deaths occurred in LMICs. Looking at TRU's key target markets, there are over 1bn women that are of eligible screening age (25-74) (Figure 7).

Figure 6: Global cervical cancer diagnostics market (US$bn)



Source: ReportLinker

Figure 7: Cervical cancer screening age population



Source: Company, WHO, IARC

China and India make up ~40% and ~30%, respectively, of this addressable population. In terms of patient population for cervical cancer (Figure 7), India is expected to surpass China by 2025.

[4] WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240030824

Timely screening allows pre-cancerous lesions to be identified at nascent stages and early treatment is likely to prevent up to 80% of the cases in these countries, which is a significant opportunity for companies such as TRU. The company's equipment does not require any sophisticated laboratory facilities and can be easily accessed by women living in remote areas, which will be a major driving factor of the equipment's usage in developing regions.

A unique strategy

Many medtechs on the ASX have a commercialisation strategy of entering larger, developed markets (particularly the USA and Europe) that have established infrastructure but also competition.

TRU's strategy has been to commercialise the technology into LMICs (Low to Middle Income Countries).

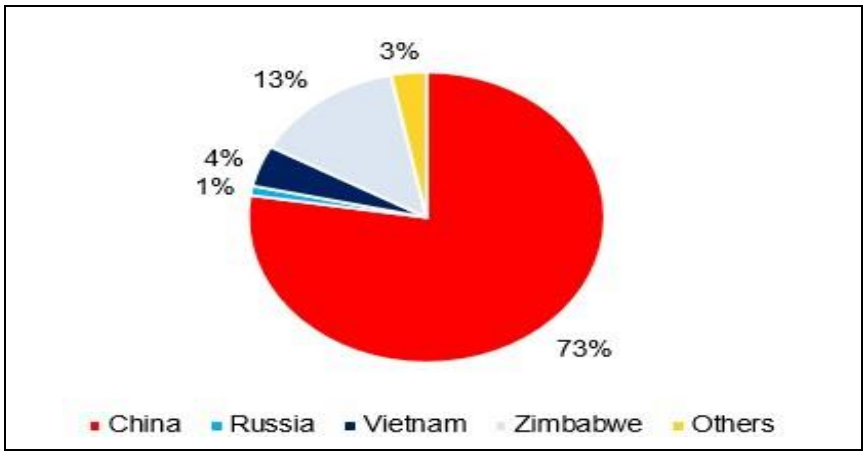
But TRU has taken a different approach. Its strategy has been to commercialise the the technology into LMICs. In doing so, TRU is taking an early-mover advantage in the cervical cancer screening space. The lack of required infrastructure and low costs mean that TRU is an ideal solution for these markets, enabling the healthcare systems to leap-frog into 21 century model of cervical cancer screening, skipping the stage of investing in costly infrastructue and healthcare facilities. TRU is entering new markets through local partnerships, collaborations or distributors (for instance, Aspironix in Eastern Europe; BettaLife in Saudi Arabia). We think it is a prudent strategy as it minimises the risk of regulatory hurdles as well as the required initial investment.

TRU is targeting both the public and private healthcare sectors for clinical use and the market for population-based screening programmes. While these mass screening programmes are ultimately, typically funded through government procurement programmes, several countries have significant non-government organisations (NGOs) and corporate-funded screening programmes. Notably, mass government screening programmes are the key to success for TRU in developing markets, for example in China. The commercial model solely relies on the appointed distributors who initiate marketing, as well as obtain support from KOLs, government officials and doctors. The distributors have also invested in clinical trials in several countries.

Current status and potential future of TRU's in its key markets

TRU's three biggest by share of revenues are China, Vietnam, Zimbabwe. Collectively, these countries account for 90% of TRU's sales, although China has easily the largest share at 73% (Figure 8). We outline the current status of TRU in its key markets below.

Figure 8: TRU FY22 revenue split by geography (NZ$m)



Source: Company

TRU's current primary markets

China – China is TRU's most important market, accounting for 73% of revenues (Figure 8) as well as the one with the highest potential. There are 404m women of screening age as well as increased government desire to meet the WHO screening target. One of the major impediments to market access has been the lack of a Made in China (MIC) device to meet the intensifying requirement of the government to adopt domestic medical devices in the public healthcare system including population based screening programs. The MIC version was awarded in 2022, overcoming this severe barrier to entry in the Chinese market. The passage of TRU through the COGA trial, which took place with over 15,000 subjects, will also help its cause in this market.

Zimbabwe – Zimbabwe is a far smaller market than China by population with only 4.59m women who are at a higher risk of developing cervical cancer due to the high positive rate of HIV in the population[5]. However, it accounted for 13% of TRU's FY23 revenue and presents large potential for market penetration given the lack of infrastructure and screening conducted. TRU has completed two pilot phase screening programs, in direct collaboration with the Ministry of Health and the National Aids Council of Zimbabwe. The most recent program saw over 10,000 women screened in 6 months[6]. Phase 2 is underway with one of these programs and a service centre is open.

Vietnam – Vietnam has 24M women of screening age, but there are no centralised screening programs as well as a lack of lab facilities and personnel for HPV or cytology-based screening. In CY22, TRU made its first commercial

[5] https://hpvcentre.net/statistics/reports/ZWE_FS.pdf
[6] https://truscreen.com/zimbabwe-pilot-project-completed/

installations in a large hospital and there are 2 more public hospitals that have completed evaluation trials and obtained Ministry of Health (MoH) approval and 6 more in the process of obtaining MoH approval. Only last month, TruScreen shipped 1800 SUS and 8 devices to Vietnam, to be installed in 8 hospitals.

Russia and Eastern Europe – Russia is the fourth largest market by revenue and has a screening population of ~42.7m. TruScreen has been distributed in Russia since 2015 and is currently distributed by JSC IMSystems. In recent months, JSC IMSystems has extended its presence to neighbouring Kazakhstan and TRU has partnered with two new distributors covering 7 countries. Strengthening KOL relationships in Poland and Serbia has been the focus, to diversify sales in Eastern and central Europe, as the ability of TRU to ship to Russia has been impeded by the Ukraine war.

Secondary markets

Mexico – Mexico has 65m women, of whom half fall within the prime cervical cancer screening age. In August last year, TRU has established a screening centre in Mexico City, operated by leading healthcare provider Mexpharm Medical Clinical. The centre will showcase the technology, act as a training centre and provide screening services to local people. TRU has also launched a leasing model with a large leasing company and pen dialogues with government bodies to replace existing method used in screening programs

MENA – In this region, TRU has made the most progress in Saudi Arabia, which has a screening population of ~7.6m. TRU has completed an evaluation project with the largest private health network, Sulaiman Al Habib Medical Group (SHMG) with commercial rollout to follow in 4QY23. Jordan and Israel are secondary markets in this region and TRU is advancing distributor presence in these countries.

India – India has substantial potential to be a huge market for TRU, not just because of the >300m screening age population but because it is substantially underpenetrated and there is little likelihood of an improvement of the situation without solutions such as TRU. A September 2022 article in the Indian Journal of Medical Research estimated that without significant improvement in cytology services in India, it will not be possible to screen even 25% of the country's female population once in a lifetime[7]. Although the government mandated a national screening programme for cervical cancer for females aged over 30 in 2016, a shortage of professionals, cytologists, colposcopists as well as healthcare infrastructure will make it difficult for existing technologies to come anywhere close to the requirement. Although TRU has been present in the country since 2017, it has been slower to gain traction compared to other jurisdictions (at least on a revenue basis). We expect this to change in the coming years as cervical cancer cases continue to rise.

[7] Indian Journal of Medical Research 156(3):p 365-367, September 2022. | DOI: 10.4103/ijmr_1571_22

Seasoned and diverse management team

The current management and board members of TRU possess substantial and diverse experience which will help the company traverse through its various development stages (Figure 9).

Figure 9: TRU's management and board members

Name and Designation	Profile
Beata Edling **Chief Executive Officer**	Dr. Edling has a Ph.D. in Medicine (UNSW) and a Masters of Business Administration (AGSM). She joined TruScreen in October 2020 as Medical Affairs and Market Access Lead and has developed an intimate knowledge of the TruScreen cervical cancer screening technology and business. Dr. Edling holds a MD from the Medical University, Gdansk, Poland. She has completed part 1 of her Fellowship with Royal College of Surgeons, Australia, PhD at the University of New South Wales, Australia, and a MBA from Sydney's Australian Graduate School of Management. She is also a graduate member of the Australian Institute of Company Directors Dr. Edling is an experienced executive who previously led large and small Medical Affairs Teams and commercialised numerous medical products with global pharmaceutical companies, Sanofi-Aventis, Shire, Eli Lily and Amgen for Australia and New Zealand. She was previously a Non-Executive Director of ASX listed Noxopharm Limited. Dr Edling is a graduate and member of the Australian Institute of Company Directors and Women on Boards.
Edmond Capcelea **Chief Technology Officer**	Mr Capcelea has a Masters degree in Engineering Physics. Edmond's previous roles include Divisional Director Head of Implants Research & Development at ASX listed Cochlear Limited where he held various positions over eighteen years, and Senior Vice President of Research and Development at Saluda Medical. Mr Capcelea has extensive experience in leading complex R&D projects from concept to commercialisation and has led the end to end product development of a wide range of Medical Devices ranging from Class I to Class III. Mr Capcelea leads all TruScreen's Technical department, covering research and development, production, quality assurance, regulatory affairs, and service and repairs. He also ensures TruScreen products are developed, manufactured, and serviced to meet the changing needs and interest of the customer whilst complying with national and international regulations.
Guy Robertson **Chief Financial Officer, Company Secretary**	Mr Robertson has a Bachelor of Commerce degree and is a member of the Institute of Chartered Accountants in Australia and New Zealand. He has over 30 years of management and leadership experience. He has extensive experience as a finance executive in Australia and Asia across a broad range of industries, in both private and listed companies. Mr Robertson is currently a director of ASX listed Hastings Technology Metals Limited and Metal Bank Limited.

Anthony (Tony) Ho **Non-executive Chairman**	Mr Ho has a Bachelor of Commerce degree from The University of New South Wales, Sydney, and is a Member of The Institute of Chartered Accountants in Australia and New Zealand, a Fellow of the Australian Institute of Company Directors, a Fellow of the Institute of Chartered Secretaries and Administrators, and the Governance Institute of Australia. He has also completed post graduate studies in Marketing at the University of Technology, Sydney. He was a past Fellow of the Australian Marketing Institute. Tony holds numerous non-executive directorships with a number of ASX and NZX listed companies. He is currently the non-executive chairman of Bioxyne Limited (ASX:BXN), Greenland Minerals Limited (ASX:GGG), and Cannasouth Limited (NZX:CBD). Tony was executive director of Arthur Yates & Co Limited, retiring from that position in April 2002. He was previously a director of Yates New Zealand Limited. Prior to joining commerce, Tony was a partner of Cox Johnston & Co, Chartered Accountants, which has since merged with Ernst & Young.
Christopher Horn **Non-executive Director**	Mr Horn has been involved with TruScreen for a number of years. He is an experienced business executive and has acted in a number of management roles including 20 years as a senior partner of KPMG and its predecessor firms. He is a director of a number of private companies across a broad range of business activities including corporate advisory, financial services, and funds management. Mr Horn is a Commerce graduate from the University of New South Wales, Sydney, Australia and a Fellow of the Institute of Chartered Accountants in Australia and New Zealand. Mr Horn is also the Chair of TruScreen's Audit, Finance and Risk Committee.
Juliet Hull **Non-executive Director**	Ms Hull has an MBA from the Macquarie Graduate School of Management, Sydney Australia, and a Bachelor of Nursing from the Auckland Technical Institute. She has more than twenty years' experience working in Asia and Pacific markets in Healthcare, in sales, Marketing and leadership. She was the General Manager/Country Director for Johnson & Johnson Medical in New Zealand and has held various roles in Johnson & Johnson in Australia and New Zealand since 2012.
Dexter Cheung **Non-executive Director**	Dr. Cheung is an experienced medical device engineer and specialist in product research and development. He is the Research and Development Manager of the respiratory humidification division of Fisher & Paykel Healthcare, an ASX/NZX listed healthcare company. With over 20 Years of experience, Dr. Cheung brings a strong understanding of manufacturing processes and has worked with suppliers and manufacturers across the glove. Dr. Cheung's technical background is in opto-electronics and expertise in medical device engineering is highly relevant to TruScreen, since its cervical cancer screening device harnesses opto-electronic signatures for screening results.
Jerry Tan **General Manager - Commercial**	Dr. Tan has extensive knowledge of the TruScreen product and has been involved in establishing the market in China and other Asian countries, including, identification of distributors, product registration, market evaluation, and the conduct of clinical trials. Dr Tan is a qualified gynaecologist, has a Master's Degree of Commerce from University of Sydney and is a Certified Practising Accountant (CPA) of Australia,and has been working with the TruScreen technology for over

	a decade. He oversees the commercial operations of TruScreen and is the commercial manager for China, Mexico, and Vietnam.

Source: Company

Valuing TRU

We value TRU based on a DCF approach at NZ$0.065 per share base case and NZ$0.133 per share bull case.

We value TRU based on a DCF approach at NZ$0.065 per share base case and NZ$0.133 per share bull case.

Our key assumptions are as follows:

- **Forecast horizon**. Our DCF is built on a 10-year explicit cashflows forecast horizon followed by a terminal value growth rate of 2%.
- **Discount rate**. We assign a discount rate of 15.8% to TRU in line with our policy in Discount Rates, implemented in July last year. In deriving our cost of equity, we calculate a revenue-weighted equity risk premium of approximately 8.0% including our standard 5% premium and a 3% risk premium considering TRU's microcap status and risks of doing business in certain jurisdictions. We use the current 10-year government bond rate (3.8%) as our risk-free rate of return and we use a 1.5x beta.
- **Revenue approach**. We apply a market share-based approach to derive TRU's expected revenues in each of its existing and potential geographical markets.

  Based on TRU's FY22 realised revenues and estimated sizes of its addressable markets, we back-solve for the company's current market shares in each of its operating regions. We assume these regional market shares will gradually expand as TRU continues to work on building its brand awareness and utility of its SUS and device and we separately model revenues for both.

  We assume 1 SUS per patient and that it is priced at US$7 each and we assume 20% growth in devices annually and that these are priced at US$3,000 each. Considering that TRU is on track to have 265 devices by March CY23, we do not think our growth assumption is unreasonable. We have modelled modest R&D tax offset assumptions for FY23 and FY24 but none thereafter. We use an exchange rate of US$1=NZ$1.62.

  We assume modest market growth in line with population trends varying between 0.8% for Vietnam and -0.4% for Russia and Eastern Europe, although we've modelled 2% growth for Zimbabwe. The only difference between our base and bull cases is that we assume it can capture slightly higher market shares. The exact premiums in growth of the company's market share vary between different markets but on average are 20-30% higher. For instance, in Zimbabwe our base case assumes a 5% share by FY32 while our bull case assumes a 7% market share. In China, meanwhile, our base case assumes an 0.35% market share by FY32 while our bull case assumes 0.4%. These figures may not seem high, but given China's 407.67m population projected for that year, this equates to 1.43m screenings in our base case and 1.63m screenings in our bull case. In Zimbabwe, meanwhile, our base case equates to 270,000 screenings by FY32 while our bull case assumes 380,000.
- **Funding**. Post TRU's rights issue of NZ$2.2M last month, our modelling assumes a further equity raise of NZ$5m in NZ24. This is sufficient to see the company to profitability.
- **Tax rate**. We assume a corporate tax rate of 30%. As TRU has significant amount of tax losses to carry forward, our base case modelling does not expect TRU to begin paying its first cash tax in FY30.
- Figure 10 on page 17 shows our DCF valuation summary and Figure 11 depicts the share price utilising different WACCs, all other things our model being equal.

Figure 10: DCF valuation summary

Valuation (NZ$'000s)	Base case	Bull case
Present value of FCF	7.43	26.20
Present value of Terminal FCF	18.42	30.66
Enterprise Value (NZ$m)	**25.85**	**56.87**
Net debt (cash)	(4.11)	(4.11)
Equity value (NZ$m)	**29.97**	**60.98**
Shares outstanding	459.4	459.4
Implied price (NZ$ cents)	**0.065**	**0.133**
Adjusted Current price (A$ cents)	0.033	0.033
Upside (%)	***97.6%***	***302.2%***

Estimates: Pitt Street Research

Figure 11: Target price sensitivity to WACC and terminal growth rate (post discount)

Sensitivity Analysis						
WAAC		*13.8%*	*14.8%*	*15.8%*	*16.8%*	*17.8%*
Terminal Growth Rate	*1.0%*	0.077	0.069	0.062	0.056	0.051
	1.5%	0.080	0.071	0.064	0.057	0.052
	2.0%	0.082	0.073	**0.065**	0.059	0.053
	2.5%	0.085	0.075	0.067	0.060	0.054
	3.0%	0.088	0.077	0.069	0.062	0.055

Estimates: Pitt Street Research

Key risks

We see following major risks facing TruScreen:

Funding risk. The company will continue to need capital investment as it commercialises its technology. There is the risk that the company may not be able to become self-sustaining with its current cash reserves or that it might need fresh capital and be unable to obtain it. Indeed, our model forecasts that without the NZ$5m raising in FY24, it will have a negative cash balance at the end of the period.

Regulatory risk. There is a risk that approval timelines in certain markets could delay commercialisation plans.

Execution risk. Our investment thesis assumes TRU's execution all goes according to plan. However, it is possible that TRU's plans could be delayed due to factors outside its control or due to poor decision making by management. This may also impact the R&D progress and funding of its pipeline products.

Technology risk. Another risk is associated TRU is that other companies may commercialise superior products and that these gain market share at TRU's expense. Although TRU's technology is superior to current alternatives, there is room for other companies to enter the industry and capture market share given the inadequacy of existing solutions.

Appendix I – Glossary

Cervical cancer – Cancer that forms in tissues of the cervix (the organ connecting the uterus and vagina). This is usually a slow-growing cancer that may exhibit symptoms but can be detected through regular tests. Cervical cancer is almost always caused by the human papillomavirus (HPV) infection.

Cervical Intraepithelial Neoplasia (CIN) – It refers to a precancerous condition involving the covering layer (epithelium) of the cervix. It can be diagnosed using a microscope. The condition is graded as CIN 1, 2 or 3, according to the thickness of the abnormal epithelium (one-third, two-thirds or the entire thickness).

Epithelium – It refers to the covering on internal and external surfaces of the body, including the lining of vessels and other small cavities.

HPV (Human Papillomavirus) – Virus spread through skin and sexual contact that is a contributing factor to cervical cancer.

Liquid-based cytology (LBC) – A method of screening for precancerous or cancerous changes of the cervix performed by scraping cells from the cervix and rinsing the sampling device into a vial containing a liquid preservative.

Negative predictive value (of a test) – The likelihood of not having the disease when the test is negative.

Pap smear – A method developed by Dr. George Papanicolaou for screening precancerous or cancerous changes of the cervix performed by scraping cells from the cervix and fixing them on a glass slide. It is also known as conventional cytology.

Sensitivity – It refers to the proportion of people who have a condition and are identified correctly by a test (true positives).

Specificity – The proportion of people who do not have a condition and are correctly identified by a test (true negatives).

Spectroscopy – The study of the effect of light when exposed to cellular tissue including measuring how the tissue reacts by chemical composition and physical properties.

Appendix II – Capital structure

Class	In million	% of fully diluted
Ordinary shares	459.4	98.9%
Unlisted options	5.0	1.1%
Fully diluted shares	**464.4**	

Source: Company

Appendix III – TRU's non-patent literature

Ma et. al (2020), *Comparison of the detection rate of cervical lesion with TruScreen, LBC test and HPV test: A Real-world study based on population screening of cervical cancer in rural areas of China.* PLoS One, Volume 15, Issue 7, Pages e0233986.

– The paper pertains to a comparative study of the detection rates of cervical lesions with TruScreen, LBC test and HPV test. The study was conducted in China, and a total of 9,972 patients were screened using TruScreen, the HPV test and the LBC test under the National Cervical Cancer Screening Program in Rural Areas (NCCSPRA). The detection rates of the three tests were compared. Based on the comparison, it was found that the HPV test should be the preferred method for cervical cancer screening in rural areas of China, if appropriate laboratories and personnel are available. However, factors such as minimal training requirements, simple operation, real-time results, and no need for invasive sample collection and specialised laboratories or cytologists, make TRU ideal for cervical cancer screening in low-resource regions.

Salazar et. al (2018), *Cervicouterine cancer screening – TruScreen vs. conventional cytology: Pilot study.* Journal of Cytology, Volume 35, Issue 3, Pages 143–148.

– The paper pertains to a study conducted (in Mexico and Latin America) to determine the sensitivity and specificity of TruScreen device and compare it with conventional cytology in cervicouterine cancer screenings. During the study, the patients were evaluated with the TruScreen device, conventional cytology, colposcopy and, if necessary, cervical biopsy. The results were analysed using statistics. Sensitivity, specificity, positive predictive value and negative predictive value of TruScreen and other methods were compared, using conventional cytology as the standard. It was seen that TruScreen demonstrated low sensitivity and high specificity when compared with conventional cytology, which had a high negative predictive value. It was concluded that more studies with a higher number of patients (with characteristics similar to those found in the region where the study was conducted) were required to ascertain the true value of TruScreen.

Yang et. al (2018), *The diagnostic accuracy of a real-time optoelectronic device in cervical cancer screening: A PRISMA-compliant systematic review and meta-analysis.* Medicine (Baltimore), Volume 97, Issue 29, Pages e11439.

– The paper describes a study pertaining to the diagnostic accuracy of the TruScreen device for uterine cervical cancer screening. A pool of databases was searched using medical subject headings (MeSH) and keywords. Title/abstract screening, full text check, data extraction and methodological quality assessment (with the QUADAS-2 tool) were performed by two reviewers independently. The pooled sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic odds ratio (DOR), the summary receiver operator characteristic curve and the area under the curve (AUC) were analysed using the Meta-DiSc software. Statistical heterogeneity was evaluated by Cochran's Q test, and meta-regression was conducted based on patient type; the possibility of publication bias was evaluated using the Deeks funnel plot in Stata software. Based on these software-based analyses, the diagnostic

accuracy of TruScreen device was found to be moderately good. The study findings are based only on Chinese patients and cannot be generalised to other populations.

Zlatkov et. al (2015), *Clinical Performance Of Different Methods For Cervical Screening.* Akush Ginekol, Volume 54, Issue 6, Pages 3–9.

– The paper pertains to a study conducted in Bulgaria to compare the clinical performance of cytology and other alternative methods, including TruScreen, for cervical screening. 317 patients were divided into four groups – the first group was screened using cytology, second using visual inspection with acetic acid (VIA), third using visual inspection with Lugol's iodine (VILI) and fourth using spectrophotometric analysis with the TruScreen device. The analysis of results concluded that cytology remains the most appropriate method for cervical cancer screening. In the absence of appropriate laboratory infrastructure or trained cytopathologists, spectrophotometric analysis with TruScreen can be used for primary cervical screening. Its main advantages lie in its user friendliness and capability to produce real-time results.

Ozgu et. al (2015), *Efficacy of a real time optoelectronic device (TruScreen) in detecting cervical intraepithelial pathologies: a prospective observational study.* Department of Gynecologic Oncology, Zekai Tahir Burak Women Health Education and Research Hospital, Ankara, Turkey, Volume 16, Issue 1, Pages 41–4.

– The paper details a study conducted in Turkey to assess the effect of the TruScreen technology in improving the sensitivity of cervical screening programmes, either alone or in combination with pap smear or HPV DNA screening. 285 patients with abnormal pap screening results were again reviewed using TruScreen and the HPV test. Consistency and differences between the tests were compared with cervical biopsy results. Based on the comparison, it was concluded that TruScreen could be used as a primary method for cervical cancer screening, especially in the absence of trained professionals and well-equipped laboratories. These advantages make it more relevant in countries with a low socioeconomic status. However, it was also concluded that the combination of TruScreen and HPV screening did not demonstrate a significant rise in the effectiveness of screening.

Du et. al (2015), *Diagnostic value of TruScreen in cervical lesions screening.* Zhonghua Yi Xue Za Zhi, Volume 95, Issue 29, Pages 2379–2381.

– The paper describes a study conducted to investigate the diagnostic value of TruScreen as a novel option for screening of cervical lesions. A total of 218 patients were screened using TruScreen and the high-risk human papillomavirus (Hr-HPV) test, and the diagnostic efficacy of the tests was compared with histopathology as the standard for diagnosis. Based on the results obtained, it was noticed that Hr-HPV test shows higher sensitivity while TruScreen shows higher specificity for cervical lesions screening. It was concluded that more studies, with larger sample sizes, will be required to accurately ascertain which method is a better triage tool.

Appendix IV – TRU's intellectual property

US 6,723,049, *Apparatus for tissue type recognition using multiple measurement techniques,* priority date 15 June 2001, invented by Victor Nickolaevich Skladnev, Christopher Kingsley Blunsden and Rita Stella.

- The patent discloses a system and a device for recognising tissue types. The device is used to apply electrical signals to the tissue via electrodes. Included circuitry and the signal processor are used to measure the impedance magnitude and phase at various pre-decided frequencies. The phase information observed at these frequencies is compared with phase information obtained from known tissue types. Based on the comparison, the tissue is categorised into one of the known types. The device is typically used for detection of cancerous or pre-cancerous tissues, especially those seen in cervical cancer.
- Applications for the patent were filed in Australia, the US and Europe, and were granted in the US and Australia.
- The US patent received a patent term extension of 111 days and is due to expire on October 03, 2022.

Appendix V – Analyst Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously, he worked as a financial journalist at Stockhead for more than three years.
- While at university, he worked for a handful of corporate advisory firms.

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